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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/089,848 | 06/25/2002 | Tomas Albrektsson | 0104-0389P | 5296 |
| 2292 | 7590 | 03/22/2004 | | |
| BIRCH STEWART KOLASCH & BIRCH | | | EXAMINER | |
| PO BOX 747 | | | BLANCO, JAVIER G | |
| FALLS CHURCH, VA 22040-0747 | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | 10 |
| DATE MAILED: 03/22/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/089,848 | ALBREKTSSON ET AL. | |
| | Examiner | Art Unit | |
| | Javier G. Blanco | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 38-74 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 June 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because:
 - a. It does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).
 - b. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required. Correction is required. See MPEP § 608.01(b).
2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:
 - a. A connecting portion (15) provided with a circumferentially oriented roughness (see claim 46).
 - b. A frusto-conical proximal section (18) provided with a screw thread profile (see claim 63).

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.
 - a. Therefore, a connecting section 15 provided with a blasted surface (see claim 45) and all configurations claimed thereof must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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- b. Therefore, a connecting section 15 provided with a completely smooth surface (see claim 50), provided with a circumferentially oriented roughness having a height less than that of the screw thread profile (see claims 47 and 48), and all configurations claimed thereof must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
- c. Therefore, a frusto-conical proximal section 18 provided with a blasted surface (see claim 57), provided with circumferential beads (see claim 64), and all configurations claimed thereof must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 43, 60, and 72 are objected to because of the following informalities:
- a. Regarding claim 43, because of the position of connecting section 15, the Examiner respectfully suggests substituting “base” (see line 3) with either --first-- or --proximal--. Also, please substitute “top” (see line 4) with either --second-- or --distal--. Appropriate correction is required.
- b. Regarding claim 60, please substitute “profiles” (see line 3) with --profile--. Appropriate correction is required.
- c. Regarding claim 72, please insert the disclosed unit of measurement after “0.1-0.5” (see line 2). Appropriate correction is required.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 48, 60, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 48, "the height" (see line 2) lacks antecedent basis.

b. Regarding claim 60, "the screw thread profiles" (see line 3) lacks antecedent basis. Claim 61 depends on claim 60.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 38-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-70 of copending Application No. 10/089,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a fixture having the same

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structural limitations (e.g., a collar section, a frusto-conical proximal section, a proximal cylindrical section, a frusto-conical connecting section, a distal cylindrical section, etc.).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 38-42, 44-55, 67, 73, and 74 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Albrektsson et al. (WO 97/25939 A1; provided in Applicants' IDS).

As seen in Figures 1-10, Albrektsson et al. disclose a femur fixture for a hip-joint prosthesis, comprising an intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position, the intraosseous anchoring structure having a head section, a collar section (flange 3), a proximal cylindrical section (fixture member 2) having a screw thread profile, a distal cylindrical section (fixture member 1) having a screw thread profile essentially the same as the screw thread profile of the proximal cylindrical section, a frusto-conical connecting section (conical end portion 7) for interconnecting the proximal and

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distal cylindrical sections, a distal end (distal end 5), and a relatively short frusto-conical proximal section at the proximal end (as shown in Figures 1 and 2, the connection between flange 3 and fixture member 2 is not at a right angle, but rather as a relatively short frusto-conical connection/section).

11. Claims 38, 39, 55-61, 63, 67, and 73 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rambert et al. (GB 2 033 755 A).

As seen in Figure 1, Rambert et al. disclose a femur fixture for a hip-joint prosthesis, comprising an intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position (see entire document), the intraosseous anchoring structure comprising a head section (cylindrical thread 4 + conical bearing 5), a collar section (plate 2) having a distal surface abutting said intraosseous anchoring structure (see Figure 1), a relatively short frusto-conical proximal section (threaded rod 7), a proximal cylindrical section (recall screw 15) having a screw thread profile, and a distal end (threaded head of 15) that projects through the lateral cortex of the femur when the intraosseous anchoring structure is in the anchored position (see Figure 1; see entire document).

12. Claims 38, 52-54, and 67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Vrespa (US 5,593,410 A).

As seen in Figure 8, Vrespa discloses a fixture having a relatively short frusto-conical proximal section (see top part of said fixture), a proximal cylindrical section (threaded shank 23), and a distal end (threaded shank 14). The frusto-conical proximal section and the proximal cylindrical section dimensioned to as to bear against the cortical bone of the bone.

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Regarding the intented use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

13. Claims 38, 52-54, and 56-67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hansson et al. (US 5,588,838 A).

As seen in Figures 1 and 3, Hansson et al. disclose a fixture having a relatively short frusto-conical proximal section (conically flaring portion 10), a proximal cylindrical section (cylinder body 1) having a screw thread profile, and a distal end. Said relatively short frusto-conical proximal section comprises circumferentially oriented micro-threads/micro-beads (character 9 or character 109).

Regarding the intented use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

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14. Claims 38, 40-50, 52-54, and 67 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kaneko (US 5,863,167 A).

As seen in Figure1, Kaneko discloses a fixture having a collar/head section (head 12), a relatively short frusto-conical proximal section (see section below the collar/head section), a proximal cylindrical section (parallel thread part 13) having a screw thread profile, a distal cylindrical section (smaller diameter parallel thread part 15) having a screw thread profile, a frusto-conical connecting section (taper thread part 14) interconnecting said proximal and distal cylindrical sections, and a tapered distal end (taper bit 16).

Regarding the intented use (i.e., for a hip-joint prosthesis, for screwing laterally into a complementary bore drilled laterally into the neck of a femur), it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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16. Claims 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson et al. (WO 97/25939 A1; provided in Applicants' IDS) in view of Hansson et al. (US 5,588,838 A).

Albrektsson et al. disclose the subject matter of claims 38-42, 44-55, 67, 73, and 74 except for particularly disclosing the frusto-conical proximal section as having a roughened surface (e.g., circumferentially oriented micro-threads, micro-beads, blasted surface). However, this is well known in the art. For example, Hansson et al. disclose a fixture comprising a relatively short frusto-conical proximal section (conically flaring portion 10) having a roughened surface (e.g., circumferentially oriented micro-threads, micro-beads, blasted surface) in order to increase the anchoring surface abutting the bone tissue and also to improve osseointegration of the fixture (see entire document). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing the frusto-conical proximal section of a fixture with a roughened surface (e.g., circumferentially oriented micro-threads, micro-beads, blasted surface), as taught by Hansson et al., with the femur fixture of Albrektsson et al., in order to increase the anchoring surface abutting the bone tissue and also to improve osseointegration of the fixture.

17. Claims 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson et al. (WO 97/25939 A1; provided in Applicants' IDS) in view of Sotereanos (US 6,284,002 B1).

Albrektsson et al. disclose the subject matter of claims 38-42, 44-55, 67, 73, and 74 except for particularly disclosing the distal surface 21 of the collar section 20 as being inclined inwardly. However, Sotereanos discloses a femur fixture comprising a collar section 20 having a distal surface 32 inclined inwardly and provided with micro-beads 22/24 in order for the collar

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section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth (see entire document). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing a femur fixture with a collar section having a distal surface inclined inwardly and provided with micro-beads, as taught by Sotereanos, with the femur fixture of Albrektsson et al., in order for the collar section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Grath (US 3,051,169), Fontenot (US 5,639,237), Stucki-McCormick (US 5,961,329), Watanabe (US 6,364,664), Baroud et al. (US 6,383,227), Schlapfer et al. (US 6,585,740), Crofford (US 6,695,883), and Albrektsson et al. (WO 93/16663).

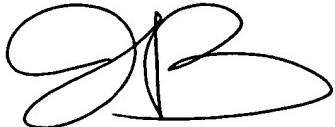
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



March 5, 2004



David H. Willse
Primary Examiner